

From: [Hebert, John](#)
To: [Baris, Reuben](#)
Subject: FW: 72500-19 efficacy studies
Date: Thursday, September 26, 2013 9:53:00 AM

From: sue@kaputproducts.com [mailto:sue@kaputproducts.com] **On Behalf Of** Sue Valentine
Sent: Friday, June 21, 2013 10:04 AM
To: Benbow, Gene
Cc: Hebert, John; Gaines, Jennifer; richard@genesislabs.com
Subject: Re: 72500-19 efficacy studies

Hi Gene:

Yes, that is correct. Well, one protocol pertains to studies with Norway Rats, and the other to House Mice. But you are right, it would be just adding another test substance to the protocols, i.e. 72500-19 with Bromadiolone and Imidacloprid.

So, we do have to wait for the conclusions of the protocol review, and if it is a favorable one, we can just add the additional test substance 72500-19.

That sounds easy enough. Let me know if there is anything else I need to be aware of.

Thanks much, Sue.

On Fri, Jun 21, 2013 at 7:18 AM, Benbow, Gene <Benbow.Gene@epa.gov> wrote:
Hi Sue,

We discussed this yesterday and I wanted to respond to you. If I understand you correctly, the 2 protocols with Jen for review right now are basically the same, the two just have different active ingredients. Is that correct? If so, then whatever conclusions we give you from our protocol reviews for these two will *equally apply* to your other product (72500-19 – the one with the rodenticide and insecticide actives). There would be no need to submit a separate protocol review for 72500-19.

Is this what you were asking?

Thanks,

Gene Benbow
Biologist
Insecticides-Rodenticides Branch
<http://epa.gov/pesticides/>

From: sue@kaputproducts.com [mailto:sue@kaputproducts.com] **On Behalf Of** Sue Valentine
Sent: Wednesday, June 19, 2013 11:32 AM
To: Benbow, Gene
Cc: Hebert, John

Subject: Re: 72500-19 efficacy studies

Hi Gene:

Any more news regarding our request to add Smacker Bait 72500-19 to the protocol with our other blocks? Let me know. Thanks, Sue

On Tue, Jun 11, 2013 at 5:14 AM, Benbow, Gene <Benbow.Gene@epa.gov> wrote:
Thank you for sending this Sue – when John gets back this week we'll discuss this with him and get back to you ASAP.

Thanks,

Gene Benbow
Biologist
Insecticides-Rodenticides Branch
<http://epa.gov/pesticides/>

From: sue@kaputproducts.com [mailto:sue@kaputproducts.com] **On Behalf Of** Sue Valentine
Sent: Monday, June 10, 2013 11:34 AM
To: Hebert, John
Cc: Benbow, Gene; richard@genesislabs.com
Subject: Re: 72500-19 efficacy studies

John:

Referring to Gene's email dated June 4th, and my discussion with Gene on June 5th, we do want to voluntarily withdraw our amendment dated May 20th, 2013 regarding EPA Reg. No. 72500-19 Smacker Bait. Please see attached letter for your files.

However, we still would like to move forward with our plans to change the formulation, which requires re-doing the studies using the whole bait block for testing. **QUESTION:** On May 14th, 2013, Scimetrics submitted two protocol reviews pertaining to our other rodent blocks (72500-7, 72500-14 and 72500-18) to do efficacy studies with new formulation and reduced number of lab animals (see OPP No. D-478827). Can we add our Smacker Bait 72500-19 to these protocols, so once approved, we could do all our block studies simultaneously?

Let's discuss when you get back to the office later this week. Thank you and best regards, Sue.

On Tue, Jun 4, 2013 at 2:10 PM, Benbow, Gene <Benbow.Gene@epa.gov> wrote:
Hi Sue,

I've discussed your response with the IRB folks and we unfortunately cannot accept these two efficacy studies. *The bait must be tested in the manner in which it is to be used in the real world.* This product is a bait block and must be tested as such – in whole block form. *The label directions for use do not instruct the applicator to break the block into smaller pieces.* Altering the bait form, regardless of the reason(s), introduces an obvious confounding variable to the study.

Please let us know how you would like to proceed.

Sincerely,

Gene Benbow
Biologist
Insecticides-Rodenticides Branch
<http://epa.gov/pesticides/>

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